K010300

AUG 1 2001

Medtronic

CONFIDENTIAL
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510(K) SUMMARY
MEDTRONIC MODEL 7495LZ EXTENSION

A. GENERAL PROVISIONS

Submitter's Name: Medtronic, Inc.

Submitter's Address: Sullivan Lake Facility
800 53rd Avenue Northeast
Columbia Heights, MN 55421

Contact Person: Pam Schaub
Senior Product Regulation Manager

Classification Name: Spinal Cord Stimulation

Common or Usual Name: Permanent Extension

Proprietary Name: Medtronic Model 7495LZ Extension

B. NAME OF PREDICATE DEVICE

MEDTRONIC MODEL 7495 EXTENSION K904409A

C. DEVICE DESCRIPTION

The Model 7495LZ Extension is a quadripolar, implantable device used to connect the receiver to the spinal cord stimulation lead. The lead connection end, or proximal end, provides "in-line" contacts that connect to the Medtronic spinal cord stimulation lead such as Model 3487A, Model 3887, Model 3888, Model 3998, or Model 3587A.

The Model 7495LZ Extension kit is provided sterile with the following accessories:

INNER PACKAGE

- Model 7495LZ Extension with set-screws
- Tunneling Tools
- Hex Wrench
- Hex Screws (2)
- Extension/lead connector boots (2)

OUTER PACKAGE

- Product Literature (IFU)

Model 7495LZ Extension

The Model 7495LZ Extension is compromised of a silicone rubber neurostimulator connector, silicone rubber body, and silicone rubber lead connector. The neurostimulator connector contains two pins that fit into the connector assembly of the receiver. The lead is inserted into the distal end of the extension and titanium setscrews are tightened to provide electrical contact between the lead and extension. The device is available in lengths from 10 cm to 110 cm.

D. INTENDED USE

The Itrel® Spinal Cord Stimulation (SCS) System is intended to deliver electrical stimulation to the spinal cord. The receiver and transmitter generate and control the stimulation, which is delivered to the spinal cord via the extension and lead electrodes at the end of the lead.

E. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Model 7495LZ Extension and accessories use common biocompatible materials, which are similar to those of currently marketed Medtronic Model 7495, in K904409A.

F. NON-CLINICAL TEST SUMMARY

The Model 7495LZ Extension and accessory has been verified as meeting specifications for design performance, material integrity, dimensions, and material biocompatibility. The results of the design verification testing were analyzed against product specifications and in comparison to the predicate device. The test results demonstrate that the product meets specification and is acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Pam Schaub
Senior Product Regulation Manager
Neurological Division
Medtronic, Inc.
800 53rd Avenue NE
Minneapolis, Minnesota 55421-1200

Re: K010300 / S1
Trade/Device Name: Medtronic Model 7495LZ Low Impedance Extension
Regulation Number: 21 CFR 882.5880
Regulatory Class: II
Product Code: GZB
Dated: January 31, 2001
Received: February 1, 2001

Dear Ms. Schaub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(K) NUMBER (IF KNOWN): K010300

DEVICE NAME: MEDTRONIC MODEL 7495LZ EXTENSION KIT

INDICATION FOR USE:

The Model 7495LZ low impedance extension is indicated to aid in the management of chronic intractable pain of the trunk or limbs.

The Model 7495LZ extension is intended for use after the successful test stimulation of the implanted lead for spinal cord stimulation (SCS). The extension provides the connection that enables the neurostimulator to deliver its programmed therapy to the lead.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010300